DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2003D–0497]

Draft Guidance for Industry on Pharmacogenomic Data Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Pharmacogenomic Data Submissions." The draft guidance provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking. The draft guidance is intended to facilitate scientific progress in the area of pharmacogenomics, which should enable the FDA to use pharmacogenomic data in regulatory policies and decision making.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time. Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and

Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Lawrence Lesko, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5690, or

Raj Puri, Center for Biologics Evaluation and Research (HFM–735), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0471.

SUPPLEMENTARY INFORMATION:

I. Background

Although the field of pharmacogenomics is in its infancy, the promise of pharmacogenomics lies in its potential to predict sources of interindividual variability in drug response (both efficacy and toxicity), thus allowing individualization of therapy to maximize effectiveness and minimize risk. Pharmaceutical sponsors have been reluctant to embark on programs of pharmacogenomic testing during the FDA-regulated phases of drug

development, due to uncertainties in how FDA will react to the data being generated.

To facilitate scientific progress in the area of pharmacogenomics, FDA is announcing the availability of a draft guidance for industry entitled "Pharmacogenomic Data Submissions." The draft guidance provides recommendations to sponsors holding INDs, NDAs, and BLAs on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking. The draft guidance is also intended to faciliate the agency's use of such data during regulatory decisionmaking.

Sponsors submitting or holding INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12 (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12)). These regulations were developed before the advent of widespread animal or human genetic or gene expression testing. FDA has received numerous inquiries about how sponsors who are conducting such testing can comply with the regulations. From a public policy perspective, a number of factors should be considered when interpreting how these regulations should apply to the developing field of pharmacogenomics. This draft guidance discusses these factors as well as the content and possible formats for submitting pharmacogenomic data to the agency in INDs, NDAs, and BLAs and how FDA expects to use the data in regulatory decisionmaking.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies

of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of

automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Pharmacogenomic Data Submissions.

Description: The draft guidance provides recommendations to sponsors submitting or holding INDs, NDAs, or BLAs on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, and BLAs for human drugs and biologics.

Burden Estimate: The draft guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the draft guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312—INDs; approved until January 1, 2006); 0910–0001 (part 314—NDAs and annual reports; approved until March 31, 2005); and 0910–0338 (approved until August 31, 2005).

The draft guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well developed exploratory tests. The submission of exploratory

pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The draft guidance describes the Voluntary Genomic Data Submission (VGDS) that can be used for such a voluntary submission. The draft guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA is requesting public comments on the following estimates of the burden of preparing a voluntary submission described in the draft guidance that should be designated as a VGDS. Based on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 20 sponsors will submit approximately 80 VGDSs and that, on average, each VGDS will take approximately 10 hours to prepare and submit to FDA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Genomic Data Submissions	20	4	80	10	800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at *http://www.fda.gov/cder/guidance/index.htm*, *http://*

www.fda.gov/cber/guidelines.htm, or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: 10/28/03

October 28, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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